DEC - 6 2000

K003483

SECTION 2.0 - SUMMARY OF SAFETY AND EFFECTIVENESS

November 7, 2000

2.1 General Information

2.1.1 Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 448-5111 Fax: (952) 448-3441

Contact Name: Jim Klosterman
Director of Quality Assurance/ Regulatory Affairs

2.1.2 Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as guides, guidewires, or spring guidewires. The current classification names, and product codes are Angiographic Guidewire (74HAP), Catheter Guidewire (74DQX), and Radiological Catheter Guidewire (74JAJ).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

The classification names listed above were originally classified as Class II devices by the Neurology (84HAD), Cardiovascular (74DQX) and Radiology (90JAJ) Review Panels, respectively.

2.1.6 Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

2.2 Labels, Labeling, and Advertising

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. Changes to the customer controlled labels, labeling, or promotional material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Statement of Availability

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.4 Device Description

2.4.1 Stainless steel steerable core with a colored (black) radiopaque polymer jacket, with a polymer/hydrophilic coating applied over the core/jacket. The guidewires are bound by the following parameters:

Outside Diameter:	.018" - .038"
Lengths:	20cm – 260cm
	Tips: Straight or shaped with various tip flexibilities

NOTE: None of these guidewires are for PTCA use.

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k) K000011]. The finished devices must meet the same basic design criteria.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined acceptance criteria.

Item	**Proposed Device Differences from LRM Predicate cleared under 510(k) K000011**
Raw Materials	**Steerable core:** **Material change from nickel/titanium material to stainless steel material.** Radiopaque jacket: No change to raw material Polymer/Hydrophilic coating: No change to raw material

Assembly Process	No change to assembly processes
Physical Characteristics	No change
Labeling/IFU	No change to labeling or IFU
Intended Use	No change to intended use
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

In order to demonstrate equivalence of the proposed device, LRM performed testing to established requirements. LRM chose a product mix of four groups of wires, based on the LRM currently marketed hydrophilic guidewire line of standard configurations, including straight and shaped distal tips. LRM samples were produced following current manufacturing processes and procedures. All samples were sterilized prior to testing.

2.5.2 Test Data

Within each of the four groups, production samples were made from the most appropriate size guidewires. For each test series, samples were produced per standard manufacturing procedures. For each test type, either fifteen (15) or ten (10) test samples were selected. Some of the tests are destructive in nature, which required the selection of additional sets of fifteen (15) or ten (10) samples to perform other tests.

The following product qualification tests were performed:

2.5.2.1 Visual: Assess the product for visual appearance, such as tip integrity and jacket durability (cuts, splits, seams, etc., any indication that the tip has been compromised).

2.5.2.2 Dimensional Measurement – Outside Diameter:

Diameter of dry guidewire
Diameter of guidewire after 10 minute normal saline soak
Diameter of guidewire after 40 minute normal saline soak

Laser micrometer measurement of the outside diameter of the guidewire at multiple body points.

2.5.2.3 Lubricity: Measures the force required to insert and withdraw the guidewire within a shaped catheter lumen standardized to each guidewire diameter.

2.5.2.4 Pull Test: Measures the strength of materials and joints in the guidewire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. Jim Klosterman
Director of Quality Assurance and Regulatory Affairs
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Dr.
Chaska, MN 55318

Re: K003483
Trade Name: Hydrophilic Coated Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: November 7, 2000
Received: November 9, 2000

Dear Mr. Klosterman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Hydrophilic Coated Guidewire

Indications for Use:

To facilitate the placement of devices for diagnostic and interventional procedures.

NOTE: These guidewires are not intended for PTCA use.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003483

Prescription Use __X__ Or Over-The-Counter Use _____
(PER 21 CFR 801.109)

PREMARKET NOTIFICATION